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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/806,878

03/23/2004

Leon M. Clements

771CG.35249

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35979 7590 07/23/2008
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EXAMINER

PHONGSVIRAJATI, POONSIN

ART UNIT

PAPER NUMBER

4176

NOTIFICATION DATE

DELIVERY MODE

07/23/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/806,878	Applicant(s) CLEMENTS ET AL.	
	Examiner SIND PHONGSVIRAJATI	Art Unit 4176	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20070914, 20070718, 20061211, 20061016,</u> | 6) <input type="checkbox"/> Other: ____. |
| <u>20060927, 20040809, and 20040628.</u> | |

DETAILED ACTION

Claim Rejections - 35 USC § 112, Second Paragraph

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 25 recites the limitation "the unit packet" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chudy et al. (US 2004/0088187 A1) in view of the Department of Health ("A Pharmacy Service for Prisoners").

7. As to **Claim 1**, Chudy teaches a method for computerized monitoring of inventory of pharmaceuticals and dispensation of prescribed medication to patients in facilities in conjunction with computerized records including an electronic medical record stored in a computer having a computer memory and containing information about a patient to receive prescribed medication and the patient's medical history (Chudy, paragraphs 0023-0025, 0120, where the patient's medical history is inherent since the pharmacist must determine what prescription has been approved for fulfillment which requires a patient's medical history), the method comprising the steps of:

- reviewing the electronic medical record to verify that the prescribed medication is suitable for the patient (Chudy, paragraphs 0077-0079, 0082);
- authorizing release of the prescribed medication for the patient if the prescribed medication has been verified as suitable for the patient (Chudy, paragraphs 0123-0124);
- labeling a unit packet of the prescribed medication for dispensing (Chudy, Fig. 6-7C);
- delivering the unit packet of the prescribed medication to a facility unit that houses the patient (Chudy, paragraph 0145);

- transferring the prescribed medication within the facility unit to administer the prescribed medication (Chudy, paragraph 0123);
- forming a record in the computer of dispensing the unit packet of the prescribed medication to the patient (Chudy, Fig. 18-28);
- forming a record in the computer indicating verification that the patient received the unit packet of the prescribed medication (Chudy, Fig. 28); and
- forming a record in the computer verifying whether the patient took the unit packet of the prescribed medication (Chudy, Fig. 28).

But Chudy does not specifically disclose the computerized method being directed towards inmates or correctional facilities. But the Department of Health does disclose using a pharmacy service for prisoners and sending prescription medication to correctional facilities (see at least sections 8-10).

It would have been obvious to one of ordinary skill in the art at the time of the invention to direct the invention of Chudy towards inmates in a prison, since inmates can be viewed as patients and the correctional facility can be viewed as a selected location the prescription medications must be delivered to. One would be motivated to provide inmates with pharmaceutical services since all prisoners should have appropriate access to a pharmacist or pharmacy staff (Department of Health, pg. 34).

8. As to **Claim 2**, Chudy teaches the method of claim 1, wherein the step of reviewing the electronic medical record includes performing the step of automatically

reviewing the electronic medical record for drug-drug interactions and allergies upon entry of a prescription into the computer (Chudy, paragraph 0149).

9. As to **Claim 3**, Chudy teaches the method of claim 1, wherein the step of reviewing the electronic medical record includes performing the step of manually reviewing the electronic medical record prior to authorizing release of the prescribed medication (Chudy, paragraph 0082).

10. As to **Claim 4**, Chudy teaches the method of claim 1, further including the step of comparing the prescribed medication with a drug formulary of approved medication stored in the computer memory upon entry of a prescription into the computer (Chudy, paragraphs 0120-0121).

11. As to **Claim 5**, Chudy teaches the method of claim 4, further including the step of recommending a substitute medication if the step of comparing the prescribed medication with the drug formulary of approved medication indicates the prescribed medication is not contained with the drug formulary of approved medication prior to the step of authorizing release of the prescribed medication (Chudy, paragraphs 0117, 120-121, where recommending a substitute may be the prescribing physician's recommendation).

12. As to **Claim 6**, Chudy teaches the method of claim 1, further including the step of verifying that the patient is the patient who has been prescribed the prescribed medication prior to forming a record in the computer of dispensing the unit packet of the prescribed medication to the patient (Chudy, Fig. 28).

13. As to **Claim 7**, Chudy teaches the method of claim 1, further including the step of adding patient enrollment data records to the electronic medical record if information related to a new patient is not already present (Chudy, paragraph 0078).

14. As to **Claim 8**, Chudy teaches the method of claim 1, further including the step of sorting each unit packet into a shipment in accordance with a shipping schedule for delivery of the unit packets to each facility after the prescribed medication has been labeled (Chudy, Fig 7E and paragraph 90).

15. As to **Claim 9**, Chudy teaches the method of claim 1, further including the step of updating the inventory of pharmaceuticals at the facility in response to the step of delivering the unit packet of the prescribed medication to a facility unit (Chudy, paragraphs 0028- 0029, 0124-0132).

16. As to **Claim 10**, Chudy teaches the method of claim 8, further including the step of caching each electronic medical record for each patient contained within each shipment scheduled to be shipped within a predefined time period prior to the step of reviewing the electronic medical record (Chudy, paragraphs 0029, where the caching of electronic medical records is inherent, since the method of Chudy uses a computer which comprises memory and a local storage (i.e. a hard drive) to cache data).

17. As to **Claim 11**, Chudy teaches the method of claim 8, further including the step of caching data related to each label to be printed for each shipment scheduled to be shipped within a predefined time period prior to printing the label (Chudy, paragraphs 0030, where the caching of electronic medical records is inherent, since the method of

Chudy uses a computer which comprises memory and a local storage (i.e. a hard drive to cache data).

18. As to **Claim 12**, Chudy teaches the method of claim 1, wherein the step of forming a record in the computer verifying whether the patient took the unit packet of the prescribed medication indicates that the patient did not take the unit packet of prescribed medication and further includes the steps of:

- subsequently locating the unit packet (Chudy, paragraphs 0033, 0090);
- returning the unit packet of prescribed medication, if suitable for future use, to a central pharmacy for reclamation (Chudy, paragraphs 0117-0118, 0153); and
- adjusting the inventory of pharmaceuticals accordingly (Chudy, paragraphs 0124-0125).

19. As to **Claim 13**, Chudy teaches the method of claim 12, further including the step of adjusting the inventory of pharmaceuticals for patients in facilities following the step of delivering the unit packet of the prescribed medication to a facility unit that houses the patient (Chudy, paragraph 0125).

20. As to **Claim 14**, Chudy teaches the method of claim 1, further including the step of automatically refilling the prescribed medication for chronic conditions if the step of reviewing the computerized patient record and the electronic medical record to verify that the prescribed medication is suitable for the patient has already been performed for the prescribed medication (Chudy, paragraph 0153, the Examiner takes the position

that the automatic refilling comprises the computer having a record that the patient is permitted to refill a stated number of times and distributing the refill if allowed).

21. As to **Claim 15**, Chudy teaches the method of claim 1, further including the step of scheduling a time period in which the prescribed medication is to be dispensed to the patient (Chudy, paragraph 0149).

22. As to **Claims 16-36**, Claims 16-36 recites substantially similar limitations to claims 1-15, and are therefore rejected using the same art and rational set forth above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SIND PHONGSVIRAJATI whose telephone number is (571) 270-5398. The examiner can normally be reached on Monday - Thursday 8:00am-5:00pm (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/S. P./
Examiner, Art Unit 4176
16 July 2008

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 4176